

Award Number: W81XWH-12-1-0037

TITLE: Using Complementary and Alternative Medicine (CAM) to Promote Stress Resilience in those with Co-Occurring Mild TBI and PTSD

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REPORT DATE: March 2014

TYPE OF REPORT: Annual Report

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE March 2014		2. REPORT TYPE annual		3. DATES COVERED 1 February 2013 - 31 January 2014	
4. TITLE AND SUBTITLE Using Complementary and Alternative Medicine (CAM) to Promote Stress Resilience in those with Co-Occurring Mild TBI and PTSD				5a. CONTRACT NUMBER W81XWH-12-1-0037	
				5b. GRANT NUMBER W81XWH-12-1-0037	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Theresa D. Hernández, Ph.D. E-Mail: Theresa.Hernandez@colorado.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of Colorado, Boulder, CO 80309				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT Mild traumatic brain injury (mTBI) and post-traumatic stress disorder (PTSD) co-occur at a high rate in Soldiers and Veterans. Despite this, there is a paucity of evidence-based treatments for those dealing with mTBI/PTSD symptoms and their exacerbation by stress. Using a placebo-controlled, randomized, blinded design, the current study is testing the following hypothesis: active acupuncture (more than Placebo) will reduce the adverse effects of stress in Veterans with co-occurring mTBI/PTSD, which will be evident in measures of anxiety, perceived stress, distress, psychiatric health, memory and in a laboratory stress task. Veterans have been recruited since regulatory approval was obtained (August 2012) and enrolled in the study in an ongoing manner, with several having already completed the study protocol or being in process. Because the study is ongoing, there are no data to report as of yet. The findings of the present study hold significant military significance: a safe, portable, low-cost, efficacious and accessible treatment strategy would benefit Veterans, family members and the military/VA health care systems. Results of the ongoing study will determine if acupuncture is such a treatment strategy.					
15. SUBJECT TERMS Recovery, outcome, complementary medicine, traumatic brain injury, PTSD, stress resilience					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU		19b. TELEPHONE NUMBER (include area code)

Table of Contents

	<u>Page</u>
Introduction.....	4
Body.....	4
Key Research Accomplishments.....	4
Reportable Outcomes.....	4
Conclusion.....	5
References.....	5
Appendices.....	5

Introduction

The currently funded study is assessing the efficacy of acupressure, a type of complementary and alternative medicine (CAM) in the Veteran population. Veterans with co-occurring mild traumatic brain injury (mTBI) and post-traumatic stress disorder (PTSD) are being recruited, consented and randomly assigned to either an active or placebo acupressure treatment series of 8 sessions. We are assessing the degree to which acupressure affects aspects of day-to-day function, such as memory, sleep, mood, psychiatric health and stress resilience. This information will help identify potential treatment strategies to improve quality of life and overall function in this particular Veteran population.

Body

Objective 1

- Task 1: The human subjects research protocol received final approval from all regulatory agencies (the VA, COMIRB and HRPO/Human Research Protections Office) as of August 2012.

Objective 2

- Tasks 1-4: The study coordinator was hired, study measures received, and study coordinator fully trained on study specific protocols, including consenting, outcome measures, equipment usage etc. Acupressure practitioner is in place and fully trained on study specific protocols. All personnel were fully trained and everything in place to begin recruiting upon final approval for the research from all regulatory agencies.

Objective 3

- Task 1: With all regulatory approvals and study personnel in place, we are currently recruiting, consenting and enrolling Veterans into the study. To date we have phone screened 232, of which 132 were determined ineligible. Of the 100 remaining, 8 declined to participate, 48 were possibly eligible but unable to participate at this time, 2 scheduled for enrollment and 42 consented. Of the 42 consented, 4 are currently enrolled, 11 are completed, 8 were determined ineligible on secondary screen, 5 withdrew from the study after consent and 14 were lost to follow.

Objective 4

- Task 1: After enrollment, participants are being randomly assigned to active or placebo intervention conditions and the study protocol is up and running, and the protocol has been completed or in the process of completion on 15 individuals.

Objective 5

- Task 1: Enter and check data in ongoing manner in preparation for analyses. The data entry and checking have begun, and are being done blinded to treatment condition. This will continue during the extension without funds period

Objective 6

- Task 1: Prepare manuscript/s and presentation at scientific conference. This will be done as soon as data checking, entry and analyses are completed. To be accomplished during the extension without funds period.

Key Research Accomplishments

- Placebo-controlled, randomized, blinded trial of acupressure in Veterans with co-occurring mTBI and PTSD is up and running.

Reportable Outcomes

- None at this time

Conclusions

Initiating a research study from the funding stage to first data collection poses a known challenge that scientists understand and expect. Initiating a research study that assesses an innovative treatment strategy like acupressure in a Federal hospital setting (Denver VA Medical Center/VAMC) poses additional challenges that the PI (Hernández) is familiar with and anticipated. While there were a few unanticipated challenges that impacted recruitment pace, these were dealt with systematically and effectively and through the appropriate regulatory channels. This successful ability to respond to challenge stems in part from the PI's experience in this type of research, as well as the significant infrastructure support from the VISN 19 MIRECC (co-PI Brenner, Director, Veterans Integrated Services Network 19, Mental Illness Research, Education and Clinical Center) and the Denver VAMC in general, has resulted in the research team successfully navigating the process and currently conducting the funded research: a placebo-controlled, randomized, blinded trial of acupressure in Veterans with co-occurring mTBI and PTSD. Because we are still enrolling participants and the rate has increased some, we requested and were granted an extension without funds.

References

None at this time.

Appendices

None at this time.